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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,551	01/31/2002	Michael A. Apicella	875.045US1	2735

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 03/25/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/066,551

Applicant(s)

APICELLA ET AL.

Examiner

Padmavathi v Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-58 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Election/Restrictions

1. Restriction to one of the following groups of invention is required under 35 U.S.C. 121:

- I. Claims 8-14, 51-52 and 56 drawn to a nucleic acid DNA and a vaccine composition comprising said DNA SEQ.ID.NOS: 6-10 and 12 classified in class 536, subclass 23.7. Further restriction to one SEQ.ID.NO required (see paragraph # 3).
- II. Claims 1-7, 15-25, and 57 drawn to a polypeptide and a vaccine composition comprising said protein SEQ.ID.NOS: 1-5 and 11 classified in class 530, subclass 350. Further restriction to one SEQ.ID.NO required (see paragraph # 3)
- III. Claims 50 and 53 drawn to an inhibitor (antibody) classified in class 530, subclass 388.6. Further restriction to one SEQ.ID.NO required (see paragraph # 3).
- IV. Claims 58 drawn to a method of preventing a female patient against Neisseria infection using DNA classified in class 514 subclass 44 Further restriction to one SEQ.ID.NO required (see paragraph # 3).
- V. Claims 26-38, 54, 57 Or 39, 43-49 drawn to a method of preventing a female patient against Neisseria infection using protein, recombinant protein or a compound that inhibits CR3, classified in class 424, 514 subclass 184.1, 2 respectively. Further restriction to one SEQ.ID.NO required (see paragraph # 3).
- VI. Claims 39-42 and 55 drawn to a method of preventing or colonization Neisseria using a compound that inhibits CR3, antibody, classified in class 424, subclass 130.1 Further restriction to one SEQ.ID.NO required (see paragraph # 3).

2. The inventions are distinct, each from the other because of the following reasons:

Group I is directed to DNA which consists of nucleic acids, Groups II is directed to polypeptides, which are made of amino acids. Invention III is drawn to an antibody, which is

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different from Inventions I-II since it has an inherent affinity, avidity, and specificity that a DNA or a simple protein is not capable of expressing. These products are different to each other structurally, biochemically and functionally and are drawn to patentably distinct inventions which have materially different physical and chemical properties and structures as represented by their divergent sequences.

Groups IV-VI are different methods utilizing different products namely DNA, protein and antibodies are considered patentably different methods. Thus the methods using different biological reagents, different method steps would result in different outcome.

Distinct Inventions

3 For each group of inventions I-VI above, restriction to one of the following SEQ.ID.NO is also required under 35 USC 121. Therefore, election is required of one of inventions I – V I and one of SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 and 12.

Inventions SEQ ID NO: 1 – 12 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions; represent structurally different polypeptides (SEQ.ID.NO: 1-5 and 11) and the polynucleotides ((SEQ.ID.NO: 6-7 and 12) encoding them. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects. Thus, each sequence is unique and patentably distinct since each sequence has a different structure with specific amino acid or nucleic acid and is identified by a specific SEQ.ID.NO. Restriction is deemed proper because these products appear to constitute patentably distinct inventions. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary,

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each such sequence is presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed SEQ.ID.NO from any group elected.

4. This application contains claims 39,43-49 directed to the following patentably distinct species of the claimed invention.

Cytochalsin D, wortmannin, an anion channel blocker, divalent cation chaelator, Clostridium neurotoxin, an inhibitor of a serine or threonine protease or Ly294002.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

5. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if

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the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Invention I is related to invention IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA of Group I can be used to prepare hybrid clones of Sarcocystis and need not be used in the inventions IV

8. Invention II is related to invention V as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of Group II can be used in immunoaffinity chromatography methods for purifying antibodies and need not be used in the inventions V.

9. Invention III is related to invention as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group III can be used in immunoaffinity chromatography for purifying antigens and need not be used in the inventions VI.

10. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either

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instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

12. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmavathi v Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on M-F (6:30A.M-4: 00 P.M.) First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

P. Baskar Ph.D.
3/19/03

LJS
LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600